JAN - 8 2001 K003339

510 (k) Summary of Safety And Effectiveness

Applicant name and address:	Collagen Matrix, Inc. 509 Commerce Street Franklin Lakes, NJ 07417
Contact person and telephone number:	Shu-Tung Li, Ph.D. President Tel: (201) 405-1477
Date of summary:	October 23, 2000
Device generic name:	Collagen Periodontal Membrane
Device trade name:	None
Predicate device:	BioMend®, Absorbable Collagen Membrane [510(k) #K924408]

Description of the device:

The Collagen Periodontal Membrane is a resorbable, type I collagen matrix of defined geometry, *in vivo* stability, permeability and mechanical strength for use in clinical periodontics.

The device is provided in three (3) sizes; 3.0 cm x 4.0 cm; 2.0 cm x 3.0 cm; and 1.5 cm x 2.0 cm. The device can be easily trimmed for a final fit during surgery to the appropriate size and shape required for the periodontal defect to be treated.

Intended Use of the Device

Collagen Periodontal Membrane is intended for use in patients with moderate to severe periodontal disease as a resorbable material for placement in periodontal defects to aid in wound healing post periodontal surgery.

Technical Characteristics

Collagen Periodontal Membrane has been designed in accordance with the accepted principles of guided tissue regeneration (GTR) as a wound healing material post

periodontal surgery. Specifically, the device is designed to be resorbable, biocompatible, cell occlusive, clinically manageable, and suturable.

Summary of Biocompatibility Studies

The following tests were performed on the Collagen Periodontal Membrane

Irritation test
Sensitization assay
Cytotoxicity
Acute Systemic toxicity
Hemocompatibility/hemolysis
Pyrogenicity
Implantation test
Mutagenicity
Subchronic toxicity
Chronic toxicity

The results demonstrated that the Collagen Periodontal Membrane is biocompatible.

Summary of *In Vivo* Resorption Studies

In vivo resorption time for the Collagen Periodontal Membrane was evaluated in a rat subcutaneous implantation model. The results of the studies showed that Collagen Periodontal Membrane has an *in vivo* resorption time from 26 to 38 weeks.

Summary of Effectiveness Data

Animal Data

The concept of GTR in periodontal surgery has been proven from animal model studies. That is, during periodontal surgery, a barrier membrane is placed over the planned and scaled tooth defect to retard and/or prevent the down growth of epithelium, and to prevent the contact of gingival connective tissue with the tooth surface. Thereby, bone, and periodontal ligament cells can repopulate the initially diseased tooth root area and the regeneration of the missing periodontal tissue can occur.

A comprehensive literature research showed that numerous materials have been studied as a barrier membrane in the GTR studies in various animal models. The materials tested

ranging from Millipore filters in the early 1980s, to teflon (generic term including the latest form of e-PTFE from W. L. Gore), to the current resorbable biopolymeric materials (collagen) and resorbable synthetic polymers of PGA/PLA materials. These studies contributed scientifically to today's understanding of GTR in periodontal surgery. The animal data provided the conclusion that the concept of GTR has been validated using either resorbable or non resorbable membranes.

Clinical Data

Results from human studies from the literature are consistent with animal studies. This GTR procedure is now fully accepted in the clinical practice of periodontics.

Similar to animal studies, the materials studied thus far, resorbable and non resorbable, are both effective as a barrier membrane in guided periodontal tissue regeneration in terms of reducing pocket depth and increasing in clinical attachment level.

Conclusion

Thus, based on the biocompatibility testing conducted on the Collagen Periodontal Membrane and literature research on the various GTR membranes, we conclude that the Collagen Periodontal Membrane is safe for implantation and is effective for GTR applications as a resorbable membrane for GTR applications in periodontal surgeries to aid in the healing of periodontal defects. The Collagen Periodontal Membrane is substantially equivalent to BioMend®.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 2001

Mr. Shu-Tung Li
President
Collagen Matrix, Incorporated
509 Commerce Street
Franklin Lakes, New Jersey 07417

Re: K003339
Trade Name: Collagen Periodontal Membrane
Regulatory Class: Unclassified
Product Code: LYC
Dated: October 24, 2000
Received: October 25, 2000

Dear Mr.Li:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ultowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003339

Device Name: Collagen Periodontal Membrane

Indications for Use:

Collagen Periodontal Membrane is intended for use in patients with moderate to severe periodontal disease as a resorbable material for placement in periodontal defects to aid in wound ~~healing~~ post periodontal surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use
(Per 21 CRF 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003339